

REMARKS

.Claims 1-17 are currently pending. Claims 5 and 9-13 were withdrawn as belonging to the non-elected invention. Claims 1-4, 6-8, and 14-17 are currently under consideration.

Substitute Specification

The Examiner noted that Applicants have not specifically identified the portions of the specification that have been amended by way of the prior submission of the substitute specification. Applicants respectfully note that the marked-up copy of the substitute specification submitted previously properly identifies those portions of the specification amended (e.g., pages 8 and 9), in full compliance with 37 CFR 1.125, as set forth in MPEP 608.01(q).

Rejections under 35 U.S.C. § 102

1. Claims 1-4, 6-8 and 17 were rejected under 35 U.S.C. § 102(b) as allegedly obvious in view of U.S. Patent Application Publication No. 2002/0012693 ("Cohen"). It is alleged that Cohen describes the claimed invention. Applicants respectfully disagree with the rejection for the following reasons.

It is well-settled that "[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." See *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990) and also MPEP § 2131 (quoting *Verdegaal Bros. v. Union Oil C. of Calif.*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). "The identical invention must be shown in as complete detail as is contained in the ...claim" *Id.* (quoting *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). Therefore, Nixon must describe each and every element of claims 1, 2 and 8-10 in order to anticipate these claims under section 102(b). However, Cohen does not meet this burden. Cohen does not teach or describe all of the claim limitations.

Applicants' claims require an inhibitor *and* a separate wound healing therapeutic agent. Cohen does not describe a separate wound-healing therapeutic agent. The Office Action describes that the active agents taught by Cohen are inhibitors (e.g., see paragraph [0022] of

Cohen, "The active agents may be protease inhibitors.""). Cohen does not teach two separate components of an active agent and a separate enzyme inhibitor.

This is in contrast to Applicants' pending claims, which require, among other things, two separate components including "a wound healing therapeutic agent and an inhibitor of the protease enzyme". Accordingly, because Cohen does not teach each and every element of the pending claims, Applicants submit that Cohen does not anticipate Applicants' claims, and request that the rejection be reconsidered and withdrawn.

2. Claims 1-4, 6, 7 and 14-17 were rejected under 35 U.S.C. § 102(a) as allegedly obvious in view of Publication No. GB 2382775 ("Cullen"). It is alleged that Cullen describes the claimed invention. Applicants respectfully disagree with the rejection for the following reasons.

Applicants' claimed invention includes a protease inhibitor and a separate active agent, each of which is a separate active component of the claimed dressing. In an aspect, the inhibitor is bound to the polymer matrix by way of a protease-cleavable linker. In this way, the wound dressing of the invention releases both protease inhibitor and therapeutic agent upon action of the proteases. Furthermore, Applicants' claimed invention comprises a matrix comprising the protease inhibitor and separate active agent.

Applicants understand Cullen to teach a wound dressing having a barrier layer to separate the therapeutic agent inside from the wound, wherein the barrier layer is comprised of a substrate for bacterial proteases found in the wound fluid. The wound dressing is comprised of a barrier layer that is broken down by the presence of host proteases in order to release the therapeutic agent. Cullen does not teach the matrix layer claimed by Applicants.

Moreover, the barrier layer taught and required by Cullen is not required by Applicants' claims. In fact, Cullen teaches that "The barrier layer is separate from the therapeutic agent" and that the therapeutic agent can be a protease inhibitor. This is in contrast to Applicants' claimed invention, in which the therapeutic agent and/or the inhibitor are either bound to or entrapped by the matrix, wherein the matrix itself is not a substrate for the wound proteases. The Cullen reference teaches that the proteases act directly upon the barrier layer that shields the therapeutic agents from the wound. This is in contrast to Applicants' claimed invention, which includes specific linker molecules which are the target of the proteases. The matrix itself is not a substrate for the proteases – Cullen does not teach this aspect of Applicants' claimed invention.

Accordingly, because Cullen does not teach each and every element of the pending claims, Applicants submit that Cullen does not anticipate Applicants' claims, and request that the rejection be reconsidered and withdrawn.

Summary

Applicants respectfully submit that the claims are in condition for allowance. An early Notice of Allowance is therefore earnestly solicited. Applicants invite the Examiner to contact the undersigned at (215) 963-5809 to clarify any unresolved issues raised by this response.

The Director is hereby authorized to charge/credit Deposit Account No. **50-0310** (Billing No. 101713-5057) for any other required fees, deficiencies or overpayments in connection with this Response.

Respectfully submitted,

BREDA MARY CULLEN ET AL.

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